

K972684

OCT 10 1997

## SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

Submitter: InnerDyne, Inc.  
5060 Amelia Earhart Dr  
Salt Lake City, Utah  
(801)-350-3600

Date Prepared: 11 July 1997

Contact: Rick Gaykowski  
Corporate Vice President,  
Regulatory Affairs and Quality Assurance

Classification Name: Percutaneous Introducer  
Common/Usual Name: Percutaneous Introducer With Sheath  
Trade/Proprietary Name: InnerDyne Radially Expanding Vascular Access System

The Radially Expanding Vascular Access System consists of an expandable sleeve assembly. The tubular member of the expandable is configured so as to be radially compressed to reduce the outside diameter of the device prior to insertion. Upon use, the expandable sleeve assembly is inserted through the skin and surrounding tissue into the selected vessel over a previously placed guidewire. (An alternative placement method would have the needle placed within the lumen of the expandable sleeve, and the combined needle and sleeve inserted into the target vessel. The guidewire would be placed and the needle removed.) The dilator/sheath assembly, which consists of a tapered dilator and sheath with integral hemostasis valve, is inserted over the guidewire through the lumen of the expandable sleeve which expands radially to accommodate the dilator/sheath. This process in turn, radially expands the surrounding tissue. Following dilation the dilator is removed, leaving the expandable sleeve and sheath with integral hemostasis valve in place to provide a sealed port for passage of instruments.

This system configuration allows the user to initially place a small diameter sheath for passage of small instruments. The sheath can then be removed from the lumen of the sleeve while leaving the sleeve inserted in the vessel. A larger diameter dilator/sheath can then be inserted through the sleeve to create a larger port for passage of the larger instruments.

The device is assembled from medical grade materials under GMP and ISO conditions. Components are molded and machined by qualified suppliers. The components are assembled and secured by adhesives, welds, and mechanical interlocks.

The subject InnerDyne, Inc., Radially Expanding Vascular Access System device is substantially equivalent to the predicate InnerDyne, Inc., Radially Expanding Dilating Introducer device (K931489). The subject Radially Expanding Vascular Access System device is similar to the referenced predicate in size, function, product dimensions and indications for use.

The Radially Expanding Vascular Access System is intended for use during minimally invasive surgery for temporary dilation access to the vasculature for passage of instruments into the vasculature. The

device is configured to be used for arterial or venous access.

The basic design principles for the subject InnerDyne, Inc., Radially Expanding Vascular Access System device and the predicate Radially Expanding Dilating Introducer device (K931489) are similar, and remain essentially unchanged from information previously provided to the Agency. The product configuration, composition, and utilized materials are similar in each of the products. The principles of operation for the InnerDyne, Inc., Radially Expanding Vascular Access System device, and the predicate Radially Expanding Dilating Introducer device (K931489) are similar. That is, each of these products employs a similar insertion technique, indications for use, contraindications for use, warnings and precautions. The subject device differs from the referenced Radially Expanding Dilating Introducer predicate (931489) only with changes to the materials used in the construction of the expanding sleeve portion and the presentation style of the product. Alternative locations and methods of sterilization are being included. The new material used in the construction of the expandable sleeve as well as the alternative sterilization locations and methods are similar to those used in the InnerDyne *Step*<sup>TM</sup> family of products ( K943253, K940232, K950632, and K950658).

From the foregoing, we conclude that the Radially Expanding Vascular Access System device is as safe and effective as currently marketed devices for the stated indications.



OCT 10 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Rick Gaykowski  
InnerDyne, Inc.  
5060 Amelia Earhart Drive  
Salt Lake City, Utah 84116

Re: K972684  
InnerDyne Radially Expanding Vascular Access System  
Regulatory Class: II (two)  
Product Code: 74 DYB  
Dated: July 11, 1997  
Received: July 17, 1997

Dear Mr. Gaykowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first name "Thomas" being the most prominent part.

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): **K972684**

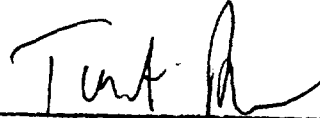
Device Name: InnerDyne, Inc., Radially Expanding Vascular Access System

Indications for Use: The InnerDyne, Inc., Radially Expanding Vascular Access System is intended to provide percutaneous access to the vasculature. The Radially Expanding Vascular Access System is indicated for the following usages:

- Percutaneous vascular access.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)




(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number

**K972684**

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)